

Appendix

Literature regarding EMCOSOY from JSR Pharma

LEADING
THE WORLD
IN EXCIPIENTS

HOME

ABOUT JRS PHARMA

WHAT'S NEW

HIGH FUNCTIONALITY EXCIPIENTS

TABLETING INGREDIENTS

REDIUM

QU



Let's Talk About Disintegrants

With nine disintegrant products, JRS Pharma offers you the broadest, most innovative selection in the industry. In addition, we created the Super Disintegrant category. But even more significant, we have the disintegrant expertise to help you achieve formulation development success.

Did you know . . . ?

- Explotab® used at high levels can serve as a sustained release matrix.
- There's an all natural Super Disintegrant called Emcosoy.
- Combining disintegrants can produce unique dissolution profiles.

Explotab® and VivaStar® brands of Sodium Starch Glycolate are best in class super disintegrants due to their unique "swelling" or the accelerated absorption of water leading to an enormous increase in their disintegrating power.

| PRODUCT | DESCRIPTION | API |
|--|--|-------------------------------|
| Explotab® and VivaStar® Sodium Starch Glycolate | Sodium Starch Glycolate NF JRS Type A Ph. Eur. BP | Direct Compressible |
| Explotab® Sodium Starch Glycolate | Sodium Starch Glycolate NF JRS Type A Ph. Eur. BP | Granulations |
| Explotab® Low pH Sodium Starch Glycolate | Sodium Starch Glycolate NF JRS Type A Ph. Eur. BP | For actives sensitive to acid |
| Explotab® Sodium Starch Glycolate | Sodium Starch Glycolate NF JRS Type A Ph. Eur. BP | Enhanced |
| VivaStar® (SE) Super Sodium Starch Glycolate | Sodium Starch Glycolate NF JRS Type A Ph. Eur. BP | Solvent Free |

Vivasol® Croscarmellose Sodium is a starch-free super disintegrant that adds excellent disintegration.

Emcosoy® (Soy Polysaccharides) is an all natural super disintegrant, which does not contain any starch. Being a dietary fiber, it has excellent application in nutritional products.

JRS Pharma LP

EMCOSOY STS IP[®]

(Soy Polysaccharides)

DESCRIPTION:

Emcosoy[®] STS IP¹, Soy Polysaccharides, is an all-natural, soft white to light-tan powder, which does not contain starch or sugar. It is derived from dehulled and defatted soybean flakes by a special process.

Emcosoy[®] STS IP is a kosher product and is manufactured without the use of bleaching agents. Emcosoy[®] STS IP typically has 75% dietary fiber with the main components including five types of higher polysaccharides: cellulose, hemicellulose, pectin, gum and mucilage. It is ideally suited for low calorie (2 kcal/g) and diabetic applications.

Emcosoy[®] STS IP is manufactured from soy that has not been genetically modified. The raw material used in producing Emcosoy[®] STS IP is segregated during harvesting and processing, and extra control are in place to ensure that such material remains segregated. Additional testing is used to test for the absence of modified gene expression. The soy used is one particular strain (STS) and the material is termed Identity Preserved (IP).

APPLICATIONS AND USES:

Emcosoy[®] STS IP exhibits excellent disintegration and improved dissolution characteristics when tablets are prepared by direct compression. Its use in soluble systems has evidenced fast and efficient disintegration of tablets prepared with a broad range of hardness values.

In most formulations, optimum concentration is approximately 6%. This may be modified to meet the disintegration/dissolution requirements of any particular formulation when incorporated in the range of 4% - 10%.

This non-ionic product contains very low concentrations [less than 5.0%] of soluble carbohydrates. This means that the amount of carbohydrates that is metabolized and thus can affect blood sugar levels is very small. For this reason the use of Emcosoy[®] STS IP in products intended for use by diabetics is considered safe. It is generally recognized as safe (GRAS) and is produced in conformance with current good manufacturing practices for (cGMP) human foods.

Emcosoy STS IP[®] STS IP is a registered trademark of JRS Pharma (Rettenmaier)
Issued March 2003

TDS.QA0.10045.00000.00
Page 1 of 3

US Office: Phone 845-878-3414 • 1-800-431-2457 • Fax 845-878-3484
UK Office: Phone +44 1737 222323 • Fax +44 1737 222545

JRS Pharma LP

EMCOSOY STS IP[®]

(Soy Polysaccharides)

PRODUCT SPECIFICATIONS:

| | |
|------------------------|--|
| 1. Appearance | Soft, white to light-tan powder |
| 2. pH | 6.5 - 7.5 |
| 3. Residual soy lipids | Not more than 2.0% |
| 4. Moisture | Not more than 8.0% |
| 5. Ash | Not more than 6.0% |
| 6. Heavy metals | Not more than 10 ppm |
| 7. Protein | Not more than 16.0% (on a moisture-free basis) |
| 8. Residual sulfites | Not more than 25 ppm |
| 9. Arsenic | Not more than 1 ppm |

Residual soy lipids, residual sulfites, and arsenic tests: Results shown represent expected limits based on historical product data. JRS Pharma warrants that this material, if tested, will conform to the specification listed for each test.

MICROBIOLOGICAL SPECIFICATIONS:

| | |
|------------------------------------|----------------------|
| 1. Total aerobic microbial count | Not more than 1000/g |
| 2. Coliforms | Not more than 10/g |
| 3. Escherichia coli | Absent in 25 g |
| 4. Salmonella species | Absent in 100 g |
| 5. Total combined yeasts and molds | Not more than 100/g |

PACKAGING:

Emcosoy[®] STS IP is available in 20 kg polyethylene-lined bags.

JRS Pharma LP

EMCOSOY STS IP[®]

(Soy Polysaccharides)

STORAGE RECOMMENDATIONS:

Emcosoy[®] STS IP should be stored in original, unopened, well-closed containers under conditions that do not typically exceed 30°C and 70% RH. When stored as recommended, Emcosoy[®] STS IP has a recommended re-evaluation period of three (3) years from the date of manufacture. An additional year can be added if the Moisture and pH re-evaluation tests are within specification.

ADDITIONAL TECHNICAL INFORMATION:

Chemical Abstract Service [CAS] Registry number: 68513-95-1

Brussels Nomenclature number: 2304 00 00 00

Emcosoy[®] STS IP Drug Master File number: pending

Although it is generally believed that protein-containing products contribute to the growth of microorganisms, Emcosoy[®] STS IP does not support such growth. It is reported that water activity values of 0.88% and 0.75% are required to promote bacterial and mold growth respectively. Since moisture contents of 10% and 20% are equivalent to water activity of 0.5% and 0.88% respectively, no possibility of microbial growth exists.

Although phytic acid and phytates may be present in certain cereal grains, including soybean and other soy products, none have been detected in Emcosoy[®] STS IP.

The protein content of Emcosoy[®] STS IP is very low and the amounts that can be fed to laboratory animals are small; therefore, it is not feasible to determine the protein efficiency ratio.

Although Emcosoy[®] STS IP contains no starch, it does produce a blue color with dilute iodine/potassium iodide solution. There are numerous references in the literature to the reaction of higher polysaccharides with iodine to give blue-colored complexes [amyloid reaction]. This reaction forms the basis for separation of individual polysaccharides from the mixtures. [Nature, Vol. 191 September 23, 1961].

WARRANTY:

The information contained in this document is believed to be accurate at the time of issuance and is offered in good faith, with no assumption of liability on the part of JRS Pharma, as a guide to the use and testing of the material, but in no way does this information constitute a performance warranty. JRS Pharma excipients are sold with the understanding that purchasers will determine the suitability of the excipients for their particular applications or purposes.

Issued March 2003

TDS.QAN.10045.00000.00

Page 3 of 3

US Office: Phone 845-878-3414 • 1-800-431-2457 • Fax 845-878-3484

UK Office: Phone +44 1737 222323 • Fax +44 1737 222545